

REMARKS

This Amendment is submitted in reply to the Final Office Action mailed on March 5, 2010. A Petition for a one month extension of time is submitted herewith this Amendment. The Director is authorized to charge \$130.00 for the Petition for a one month extension of time and any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712038-00306 on the account statement.

Claims 1, 4, 7-11, 14, 18-21 and 24-33 are pending in this application. Claims 2-3, 5-6, 12-13, 15-17 and 21-26 were previously canceled or withdrawn. In the Office Action, Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. §112 and §103. In response, the specification and Claims 1, 11, 27, and 32-33 have been amended. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be reconsidered and withdrawn.

In the Office Action, the specification is objected to under 35 U.S.C. 132(a) because the Patent Office alleges it introduces new matter into the disclosure. Specifically, the Patent Office alleges that the deletion of the paragraph “In an embodiment, a chewing gum comprising Erospicata oil and a cooling agent selected from the group consisting of menthol, methol glyceryl ether, N,2,3-trimethyl-2-isopropyl-butanamide and menthyl glutarate or combinations thereof” from page 4, lines 3-5 of the present specification, made in order to clarify the definition of “cooling agents” (which is defined as non-menthol cooling agents), constitutes new matter. See, Office Action, page 2, line 15-page 3, line 3.

In response, Applicants have amended the specification to reinsert the majority of the paragraph at page 4, lines 3-5. However, the Applicants have deleted the cooling agent “menthol” from the paragraph such that the paragraph now reads, “In an embodiment, a chewing gum comprising Erospicata oil and a cooling agent selected from the group consisting of menthol glyceryl ether, N,2,3-trimethyl-2-isopropyl-butanamide, and menthyl glutarate or combinations thereof.” Neither the reinsertion of the paragraph nor the deletion of the cooling agent menthol adds new matter. Indeed, Applicants respectfully submit that the skilled artisan would understand that the deleted cooling agent menthol was included in the application by mistake and without any deceptive intent.

For example, the Manual of Patent Examining Procedure (“MPEP”) states that “[a]n amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction.” See, MPEP, §2163.07 (citing *In re Oda*, 443 F.2d 1200 (CCPA 1971)). In the case of *In re Oda*, the Court found that Applicants had sufficiently demonstrated that the foreign language translation from “nitric acid” to “nitrous acid” was in error. Applicants demonstrated such error via the submission of arguments and an affidavit from a skilled artisan. 443 F.2d at 1205-07.

Similarly, one of ordinary skill in the art would immediately appreciate that that the cooling agent menthol in the paragraph at page 4, lines 3-5 in the specification was included erroneously by Applicants. For example, Applicants explicitly defined “cooling agents” in the specification as “non-menthol cooling agents.” See, specification, page 1, lines 20-21 (emphasis added). Applicants specifically defined this phrase in accordance with Applicants’ right to be her own lexicographer. Specifically, where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999). Accordingly, Applicants’ intention was clearly to define “cooling agents” as “non-menthol cooling agents.”

Further, there are several locations in the specification where Applicants provide examples of what may be used as a “cooling agent.” In the specification at, for example, page 2, line 26-page 3, line 2 and page 3, lines 20-25, Applicants state that “cooling agents” may include N-ethyl-p-menthane-3-carboxamide, N,2,3-trimethyl-2-isopropyl-butanamide, menthyl glutarate, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, 3,3,5-trimethylcyclohexanol, isopulegol, and combinations thereof. Applicants note that menthol is not included in the listing of possible “cooling agents.” In addition, the specification also clearly requires, in an embodiment, Erosipata oil, a cooling agent and menthol. See, specification, page 1, lines 14-21; page 4, lines 1-2; Table 6. Applicants submit that it would not make sense to require these three ingredients if menthol were intended to be included as a cooling agent.

For at least the above-mentioned reasons, Applicants respectfully submit that the reinsertion of the above-mentioned paragraph and deletion of above mentioned-cooling agent menthol does not constitute new matter.

Accordingly, Applicants respectfully request that the objection to the specification under 35 U.S.C. §132(a), be reconsidered and withdrawn.

In the Office Action, Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Specifically, the Patent Office alleges that the claims recite the limitation “wherein the menthol comprises at least 0.02% by weight” and [that] the specification does not appear to support this limitation because the recitation of “at least” supports...various amounts greater than 0.02 and the specification only appears to support menthol with a concentration of 0.02%, 0.03% and 0.1 to 20% in the case of edible film formulations” See, Office Action, page 3, lines 18-25. Therefore, the Patent Office alleges that this is new matter. See, Office Action, page 3, lines 23-25.

In response, Applicants have amended Claims 1, 11, 27, 32-33 to delete the phrase “wherein the menthol comprises at least 0.02% by weight.” The deletion of the phrase does not add new matter. As such, Applicants respectfully submit that these rejections are now rendered moot.

In the Office Action, Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,009,893 to Cherukuri et al. (“*Cherukuri*”) in view of U.S. Patent No. 4,980,169 to Oppenheimer et al. (“*Oppenheimer*”) and Plant Patent No. 8,645 to Sturtz (“*Sturtz*”). For at least the reasons set forth below, Applicants respectfully submit that the rejections should be reconsidered and withdrawn.

Independent Claims 1 and 11 recite, in part, a product comprising Erospicata oil, menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product. Similarly, independent Claims 27 and 32 recite, in part, a method comprising the steps of adding to a product Erospicata oil, menthol, a heating agent and a cooling agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product. Independent Claim 33 recites, in part, a method of reducing the amount of peppermint flavor required to achieve an organoleptic effect in a product comprising the steps of manufacturing the product with Erospicata oil, menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product.

The present claims provide a product including Erospicata oil, a non-menthol cooling agent and menthol. See, specification, page 1, paragraph 4; paragraph 12, lines 1-4; page 2, .

paragraph 19. The unique combination of Erospicata oil and a non-menthol cooling agent provides a novel flavor which reduces the cost of peppermint-flavored products. See, specification, page 1, paragraph 4, lines 6-12; paragraph 5, lines 1-6. Menthol may also be included in the product as an additional flavoring agent to kill germs. See, specification, page 6, paragraph 68, lines 1-2 and 6-12. Furthermore, by including the Erospicata oil in an amount between 0.01% and 5% by weight of the product, the product provides a unique flavoring benefit. See, specification, page 2, paragraph 22; page 5, paragraph 54, lines 1-3; Tables 1-2 and 6. In contrast, the cited references fail to disclose a product comprising Erospicata oil, an effective amount of menthol and a cooling agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product for at least the reasons set forth below. Applicants respectfully submit that the cited references are deficient with respect to the present claims because they fail to disclose or suggest every element of the present claims and thus fail to render the claimed subject matter obvious.

For example, *Cherukuri*, *Oppenheimer*, and *Sturtz* fail to disclose or suggest a consumable oral product comprising Erospicata oil, as required, in part, by all of the independent Claims 1, 11, 27 and 32-33 and Claims 4, 7-10, 14, 18-20 and 28-31 that depend therefrom.. In fact, neither *Sturtz*, *Cherukuri* or *Oppenheimer* disclose any amounts of Erospicata oil in any confectionery product at any place in the disclosures.

Sturtz is entirely directed to a low-menthol Erospicata plant and fails to mention the use of Erospicata in any confectionery product whatsoever. See, *Sturtz*, Title; Abstract, lines 1-4; Column 1, lines 19-26. *Cherukuri* is entirely directed to an oral composition comprising menthol and N-substituted-p-menthane carboxamide and fails to even mention Erospicata oil. See, *Cherukuri*, page 1, column 2, lines 34-38. *Oppenheimer* is entirely directed to an oral composition containing a volatile oil such as menthol in combination with a sensorially undetectable amount of a volatile oil modifying agent. However, *Oppenheimer* also fails to disclose or suggest Erospicata oil. See, *Oppenheimer*, page 2, column 2, lines 5-12. Applicants respectfully submit that because *Sturtz*, *Cherukuri*, and *Oppenheimer* fail to disclose or suggest each and every element of the present claims, the cited references fail to render the claimed subject matter obvious.

Applicants further submit that, even if the references disclose every element of the prior claims, one of ordinary skill in the art would have no reason to combine the cited references

because *Sturtz* teaches away from both *Cherukuri* and *Oppenheimer*, as well as the present claims. For example, *Sturtz* is entirely directed to providing as low a menthol content as possible while also providing peppermint-like organoleptic properties. See, *Sturtz*, column 2, lines 28-31. *Sturtz* specifically teaches that menthol is undesirable in ingestible products “because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28. In fact, *Sturtz* states that menthol is “substantially absent from the oil” and that “[t]he low menthol content of the essential oil is important” to avoid nasal and gastrointestinal problems. See, *Sturtz*, column 2, lines 24-26 and 28-31.

In contrast, *Cherukuri* is entirely directed to an oral composition requiring both menthol and N-substituted-p-menthane carboxamide compound. See, *Cherukuri*, page 1, column 2, lines 34-38. *Cherukuri* specifically teaches that “[t]he presence of only one of these components will not provide the desired results,” and that “[a] combination of these two ingredients when used in specific amounts overcomes the deficiencies of each component.” See, *Cherukuri*, page 2, column 2, lines 5-7 and lines 16-18. Similarly, the present claims require menthol in an oral consumable product.

Also in contrast to *Sturtz*, *Oppenheimer* is entirely directed to an oral composition containing a volatile oil such as menthol in combination with a sensorially undetectable amount of a volatile oil modifying agent. See, *Oppenheimer*, page 2, column 2, lines 5-12. *Oppenheimer* specifically teaches that menthol’s “medicinal effect is known in the art,” and that menthol “is useful to relieve local irritations in the throat and mouth.” See, *Oppenheimer*, page 1, column 1, lines 45-48. This is directly antithetical to the proposition from *Sturtz*, which specifically teaches that menthol is undesirable in ingestible products “because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28.. Thus, *Sturtz* expressly teaches away from using any menthol in ingestible products as disclosed by both *Cherukuri* and *Oppenheimer*, as well as the present claims.

The Patent Office asserts that one of ordinary skill in the art would combine *Cherukuri*, *Oppenheimer*, and *Sturtz* “to use a flavor that will give the composition the taste of peppermint oil without adding additional menthol ” See, Final Office Action, page 6, lines 16-22. However, as discussed previously, the present claims require additional menthol in an oral consumable product. *Sturtz* teaches away from the use of any menthol in ingestible products, regardless of whether the menthol is used to give the composition the taste of peppermint. *Sturtz* expressly

states that menthol, without any limitation as to what the menthol is used for, “irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28. As such, *Sturtz* teaches away from the use of any menthol in oral consumable products. Although the Erospicata oil of *Sturtz* may contain a very small amount of menthol (only 0.05%, which *Sturtz* describes as being “substantially absent” from the oil), *Sturtz* expressly teaches away from using any additional menthol apart from that present in the Erospicata oil. See, *Sturtz*, column 2, lines 24-34; Table 1. By expressly disparaging the use of menthol in ingestible products, *Sturtz* teaches away from using any additional menthol not already present in its Erospicata oil.

The Patent Office cannot pick and choose specific teachings of the references to meet the claimed limitations but rather must consider the teachings of each reference as a whole. See, MPEP Section 2142 (2009). Regardless of which cooling agent one of ordinary skill in the art may choose, the fact remains that *Sturtz* as a whole expressly teaches away from using any menthol in addition to that contained in its Erospicata oil. See, *Sturtz*, column 2, lines 24-28. Because *Oppenheimer* discloses that menthol may be used as a cooling agent and for its medicinal properties, Applicants respectfully submit that *Sturtz* expressly teaches away from *Oppenheimer*. Because *Cherukuri* specifically requires that menthol be used in order to achieve a longer lasting cooling sensation, Applicants respectfully submit that *Sturtz* expressly teaches away from *Cherukuri*. Because *Sturtz* is entirely directed to an oil with as low a menthol content as possible to avoid gastrointestinal and nasal irritation, *Sturtz* teaches away from adding menthol to an oral product as taught by Cherukuri, Oppenheimer, and the present claims.

In sum, the Patent Office has failed to consider the cited references as a whole including those portions teaching against or away from each other and/or the claimed invention. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443, 448-49 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by [Applicants].” *Monarch Knitting Machinery Corp. v. Fukuwara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998). Specifically, the Patent Office has continued to ignore the express teaching in *Sturtz* that menthol is undesirable in oral products “because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28. Because *Sturtz* teaches away

from *Cherukuri*, *Oppenheimer*, and the present claims, one of ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

Applicants respectfully submit that unless those portions of the art that teach away from the combination that is proposed are considered, almost every invention would be obvious, hence the reason the courts have time and time again cautioned against such a hindsight analysis. Therefore, Applicants respectfully submit that the Patent Office has improperly applied hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Applicants respectfully submit that such a reason is not present in the instant case.

Further, the Federal Circuit has specifically found that references are not properly combinable or modifiable if their intended purpose is destroyed. For instance, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). This certainly applies where *Cherukuri* is not concerned with reducing the amount of menthol used in the compositions since the entire purpose of the composition is for long-lasting non-bitter cooling flavor as provided by the addition of a N-substituted-p-menthane carboxamide compound to menthol, where menthol is a necessary component in order to achieve the long-lasting non-bitter cooling flavor. As such, any composition of *Cherukuri* would render the Erospicata disclosed in *Sturz* useless because *Sturz* is directed to the use of a “substantially absent” amount of menthol contained in its Erospicata oil. See, *Sturtz*, column 2, lines 24-26. For at least these reasons, Applicants respectfully submit that the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

For at least the reasons discussed above, the combination of *Cherukuri* in view of *Oppenheimer* and *Sturtz* is improper or fails to disclose or suggest every element of the present claims and thus fails to render the claimed subject matter obvious. Additionally, *Sturtz* teaches away from adding menthol to an oral product as taught by *Cherukuri*, *Oppenheimer*, and the present claims. Therefore, one of ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 1, 4, 7-11, 14, 18-20 and 27-33 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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Dated: July 1, 2010 _____